Document 936

Filed 05/30/25

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Case 3:21-cv-04062-EMC

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on July 9, 2025, at 1:30 p.m., or as soon as is convenient for the Court, the Honorable Edward M. Chen, in Courtroom 5 on the 17th floor of the Phillip Burton Federal Building and U.S. Courthouse at 450 Golden Gate Avenue, San Francisco, CA 94102, Plaintiff and Counterclaim-Defendant Guardant Health, Inc. will and does move for an order unsealing the court exhibit identified at trial on November 18, 2024 and included as Exhibit EE to the Declaration of Craig Harbaugh in support of Guardant's Motion for Attorneys' Fees & Costs, Dkt. 885 (Under Seal Version); Dkt 891 (Redacted Version), under Civil Local Rule 79-5(g)(3) and the First Amendment.

This Motion is based on this Notice of Motion and Motion, the attached Memorandum of Points and Authorities, the accompanying Declaration of Chase Scolnick and the exhibit thereto, as well as other written or oral argument presented to the Court.

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Dated: May 30, 2025 KELLER ANDERLE SCOLNICK LLP

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By: /s/ Chase Scolnick

Chase Scolnick

Attorneys for Plaintiff/Counterclaim-Defendant GUARDANT HEALTH, INC.

I. Introduction

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Guardant seeks to vindicate the public's fundamental right to access court records bearing on the integrity of Natera's claims and the clinical validation study Natera presented at trial (the "Reinert Study") by seeking the unsealing of a Natera email that is nearly 7 years old and contains no conceivable trade secrets or competitively sensitive information. See L.R. 79-5(g)(3).

During trial, the Court entered the email, dated June 27, 2018 ("June 27, 2018 Email"), as a "tendered exhibit that was not admitted," Trial Tr. vol. 8, at 1955-56, and Guardant attached it as an exhibit to its pending post-trial motion for attorneys' fees, Dkt. 885 (Under Seal Version); Dkt 891 (Redacted Version), as Exhibit EE to the accompanying Declaration of C. Harbaugh. At the time the Court accepted the email as a tendered exhibit, Natera made no argument for it to be under seal. Guardant filed the email under seal as part of its motion for attorneys' fees, Dkt. 885, because Natera stamped the email "Confidential," yet Natera has not filed any document over the last 4+ months explaining why it should remain under seal. See L.R. 79-5(f)(3) (requiring party seeking to maintain a document under seal to "file a statement and/or declaration" within 7 days).

Furthermore, there is no reason, much less a compelling reason, for this email to remain under seal. The email is 7 years old and contains no trade secrets, no competitively sensitive information, and no confidential medical records. While Natera may gripe that the email could cause it embarrassment, paint it in an unfavorable light, or lead to renewed scrutiny of the Reinert Study, those are insufficient reasons to overcome the strong presumption in favor of public access. See Kamakana v. City & Cnty. of Honolulu, 447 F.3d 1172, 1179 (9th Cir. 2006) ("The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records.").

Even if Natera could make out a compelling reason to seal this email (which it cannot), the overriding public interest would require it to be unsealed. The Ninth Circuit repeatedly has affirmed that the public's interest in accessing court records is at its zenith when those records expose matters of public concern. This is precisely the case here: the Natera email, when viewed with evidence already in the public record from trial, shows that Natera's senior executives knew that combining the results from Signatera with the results from a separate bespoke assay designed by researchers at Aarhus University into the Reinert Study would misrepresent the performance of Signatera. *See* Trial Tr. vol. 8, at 1895 (Guardant's counsel arguing "here you have Natera internally acknowledging that it would be improper to do this, and they went ahead and did it anyway."). Yet, to Guardant's knowledge, Natera has made no effort to correct or rescind the Reinert Study. Rather, Natera continues to tout the Reinert Study as the foundational validation study for Signatera. The public has a substantial interest in a large healthcare company that manipulated the data in a peer-reviewed publication. Thus, Guardant requests that the Court unseal this email.

II. Background on Natera's June 27, 2018 Email

Natera's comparative advertisements — built on a false comparison between the clinical validation studies of Signatera and Reveal — have been the central issue in this case. For years, Natera waged a campaign of unfounded and misleading attacks on the integrity of Guardant's clinical validation study for Reveal and the professional reputations of the two principal investigators of that study (Drs. Corcoran and Parikh from Havard Medical School). *See*, *e.g.*, Trial Tr. vol. 9, at 2069:5-6 (Natera's Closing Argument) ("And that's because the results of the Parikh study were fabricated or fraudulently created."); *id.* at 2129:8-9 ("The bottom line is their statements [Guardant's statements based on the Parikh Study] were false and misleading and fraudulent and dangerous in every respect."). Natera's attacks on Guardant were thoroughly and convincingly rebutted by Guardant's witnesses, whose testimony remained clear, consistent, and credible throughout the trial. The jury ultimately rejected Natera's allegations in full.

While leveling those accusations, Natera attempted to conceal that it was, in fact, Natera — not Guardant — that manipulated data to inflate the apparent performance of its own assay. Natera made the definitions of "prospective" and "blinded" central to its attacks on Reveal's validation study, yet Natera fought to prevent any scrutiny of how those terms were used by Natera itself and Dr. Claus Andersen, the lead author of the Reinert Study. After the Court ruled in the motions *in limine* that evidence regarding the Reinert Study would be relevant and admissible because it "sheds light on the meaning of 'prospective' and 'blinded,'" Dkt. 509, at 15, Natera falsely represented to the Danish authorities that any evidence from Dr. Andersen "is unlikely to be admissible in the US

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trial." Dkt. 664, at 2 (Letter from Guardant's counsel explaining status of Danish discovery).

Natera was desperate to exclude Dr. Andersen's testimony because it would contradict key statements by Natera's witnesses under oath and by Natera to the Court. Throughout this case, Natera's witnesses testified at depositions that the Reinert Study showed only the performance of Signatera and did not include the results of the distinct "Pool 2" analysis, which was based on a test custom designed by Natera's collaborators at Aarhus University after seeing the results from Signatera and comparing those results with the recurrence status of each patient. Natera repeated those statements to the Court: "Dr. Andersen's [Pool 2] comparison of Signatera with ddPCR did not serve to bolster Signatera's performance." Dkt. 277-5, at 15 n.15. This Court relied on Natera's misrepresentations and granted its motion for summary judgement with respect to Guardant's unclean hands defense. Dkt. 326, at 43.

The evidence and testimony at trial revealed Natera's representations were false. Trial Exhibit 261 contains Natera's presentation dated June 22, 2018, that explains the extensive reanalysis and new analyses Natera performed on the Reinert Study's samples after being unblinded. Trial Exhibit 261 shows how Pool 2 involved a completely different design from Natera's Signatera. See Trial Ex. 261, at 16 ("Design strategy: One ddPCR target for each patient; 2 hotspot mutations; Actionable variants."). Natera's documents acknowledge that the Pool 2 analysis was based on a "[1]ist of actionable and hotspot mutations . . . already provided by Aarhus," not the set of mutations selected by Natera for use in Signatera. Trial Ex. 395, at 2. Natera's own documents also acknowledge that the Pool 2 analysis was designed after Natera was unblinded and checked the initial results from Signatera against each patient's recurrence status (the "clinical truth"). See Trial Ex. 381, at 2 ("Signatera Pool 2: This pool is expected to get designed after plasma sequencing

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¹ After Natera's initial attempts to thwart the deposition of Dr. Andersen failed, Natera insisted that despite Dr. Andersen being fluent in English (Natera only communicated with him in English) that the deposition be in Danish. Dkt. 765, at 1. Natera further insisted that only Danish counsel should be allowed to question him. Dkt. 765-2, at 2 (Natera "objects to allowing Guardant's American lawyers to conduct the questioning"). Natera then demanded, with a straight face, that Danish counsel not be allowed access to any confidential materials produced in this litigation. Dkt. 765, at 2. Guardant jumped through multiple hoops, including providing a simultaneous English translation by an E.U. certified interpreter and a simultaneous transcription by a U.S. certified court reporter. Rather than object to that translation at the time — or retain its own interpreter — Natera laid in wait and right before trial raised frivolous objections to the translation. Dkt. 763.

data for AACR has been generated and cross-checked against clinical truth."). Dr. Andersen confirmed that Pool 2 searched for a set of 16 mutations that was different from the mutations searched for by Signatera. C. Scolnick Decl., Ex. A, Andersen Dep. (Day One) at 76:13-17 & 77:6-9 (as played at trial) ("Q: So Pool 2 was designed after Natera has learned which patient[s] had had relapses, so after they had been unblinded? A: Yes.... Q: Pool 2 uses another set of 16 mutations to search for them what was used in Pool 1? A: Yes.").

Trial Exhibit 261 further shows the discordant results between Pool 1 (Signatera) and Pool 2 (Aarhus-bespoke assay) — *i.e.*, patient samples that Pool 2 correctly identified as positive that were missed by Signatera. Trial Ex. 261, at 21 ("Pool 2: ddPCR assay performance on samples missed by Signatera but detected by ddPCR.").² All of this occurred about a year before the Reinert Study was published in JAMA Oncology in May 2019. Trial Ex. 4. Dr. Andersen readily confirmed that for the final Reinert Study, the results from Pool 1 (Signatera) and Pool 2 (Aarhus-bespoke assay) were combined into one set of results. C. Scolnick Decl., Ex. A, Andresen Dep. (Day One) at 90:16-23 (as played at trial) ("Q: So Pool 1 and Pool 2 findings have been pooled into one. But Pool 2 was carried out after Natera had been unblinded? A: Correct."). Nothing in the Reinert Study, or Natera's advertising based on the Reinert Study, disclosed that the results were not purely from Signatera but rather incorporated results from an entirely different test designed after unblinding.

At trial, Natera continued to deny any manipulation of the Reinert Study, and Natera's witnesses claimed not to understand Dr. Andersen's damaging testimony. Trial Tr. vol. 8, at 1782:19-25 ("That part of the testimony was a little hard to follow, truthfully.") (M. Metzker); *id.* at 1845:5 ("I honestly did not understand Dr. Andersen's testimony.") (R. Betensky). When Natera's expert, Michael Metzker, dismissed Dr. Andersen's testimony as "hard to follow," Guardant moved to introduce the June 27, 2018 Email in which Natera senior executives discussed how combining the Pool 1 and Pool 2

² Trial Exhibit 261 also shows other additional new analyses Natera performed on the Reinert Study samples, including an "Additional Signatera pool . . . designed for 4 patients based on synchronous tumor WES," which like Pool 2 led to different results from Signatera. Trial Ex. 261, at 23.

results would be improper.³ *Id.* at 1782-85. The Court sustained Natera's objection on foundation grounds — preventing the jury from seeing the document. *Id.* at 1785.

The parties later discussed the June 27, 2018 Email with the Court outside the presence of the jury when Guardant moved to present the document in its rebuttal case. *Id.* at 1892-97. Guardant explained:

[The June 27, 2018 Email] brings it all together. Because what we have from Dr. Andersen is they were unblinded on March 28. They did these reanalyses. Pool 2 was added to the final results. And here you have Natera internally acknowledging that it would be improper to do this, and they went ahead and did it anyway.

Id. at 1895:20-24. The Court denied Guardant's request to admit the email because it was not identified earlier or offered through a sponsoring witness. *Id.* at 1896-97. The Court accepted the email as a tendered court exhibit that was not admitted to the jury. *See id.* at 1955-56.

The June 27, 2018 Email is attached to Guardant's pending motion for attorneys' fees. *See* Dkt. 885-2, at 13-14 (explaining relevance of the email); Dkt. 885-8 (June 27, 2018 Email filed under seal). Guardant's motion explains how the email provides further evidence of the unreasonable manner in which Natera litigated this case — Natera's false representations to the Court in the context of summary judgment motions, Natera's ill-intent in trying to thwart the deposition of Dr. Andersen, and Natera's unreasonable attacks on the Parikh Study when the truth is that it was Natera that manipulated data in its clinical validation study. Dkt. 885-2, at 13-14.

III. Statement of Issues To Be Decided

Whether the June 27, 2018 Email should be unsealed because it is 7 years old and there are no compelling reasons to overcome the strong presumption in favor of public access to court documents, particularly documents that pertain to matters of public interest and public health.

IV. <u>Legal Standards</u>

"[C]ourts of this country recognize a general right to inspect and copy public documents, including judicial records and documents." *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597

³ During the cross examination, Guardant's counsel quoted directly from this email, drawing attention to a statement from Natera's Chief Medical Officer, Alex Aleshin, that makes clear Natera knew that incorporating the Pool 2 results would be improper manipulation of the data. *Id.* at 1784:18-23.

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(1978). Accordingly, in assessing whether to unseal a document, there is "a strong presumption in favor of access to court records." Ctr. for Auto Safety v. Chrysler Grp., LLC, 809 F.3d 1092, 1096 (9th Cir. 2016) (quoting Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1135 (9th Cir. 2003)). This strong presumption in favor of public access arises from the need for the "public's understanding of the judicial process and of significant public events." Valley Broad. Co. v. U.S. Dist. Ct. for Dist. of Nev., 798 F.2d 1289, 1294 (9th Cir. 1986).

A party seeking to seal a court document, therefore, "bears the burden of overcoming this strong presumption by meeting the 'compelling reasons' standard." Ctr. for Auto Safety, 809 F.3d at 1096 (quoting Kamakana v. City and Cnty. of Honolulu, 447 F.3d 1172, 1178 (9th Cir. 2006)). That party "must articulate compelling reasons supported by specific factual findings, that outweigh the general history of access and the public policies favoring disclosure" Kamakana, 447 F.3d at 1178-79 (quotation marks omitted). The court, in turn, must "conscientiously balance the competing interests of the public and the party who seeks to keep certain judicial records secret." Id. at 1179 (quotation marks omitted). To seal a document, the court "must 'base its decision on a compelling reason and articulate the factual basis for its ruling, without relying on hypothesis or conjecture." Id. (quoting Hagestad v. Tragesser, 49 F.3d 1430, 1434 (9th Cir. 1995)).

"What constitutes a 'compelling reason'" to seal a court document "is 'best left to the sound discretion of the trial court." Ctr. for Auto Safety, 809 F.3d at 1097 (quoting Nixon, 435 U.S. at 599). "The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records." Kamakana, 447 F.3d at 1179 (emphasis added). Nor is it a sufficiently compelling reason that a party designated materials as confidential pursuant to a protective order. See Exeltis USA Inc. v. First Databank, Inc., 2020 WL 2838812, at *2 (N.D. Cal. June 1, 2020) ("[A] designation of confidentiality is not sufficient to establish that a document is sealable. 'Confidential' is merely

⁴ An exception to the "compelling reasons" standard exists "for sealed materials attached to a discovery motion unrelated to the merits of the case." Ctr. for Auto Safety, 809 F.3d at 1097. In those circumstances, the party seeking to a seal a document need only satisfy the "good cause" standard. Id. "A party asserting good cause bears the burden, for each particular document it seeks to protect, of showing that specific prejudice or harm will result if no protective order is granted." Foltz, 331 F.3d at 1130.

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the parties' initial designation of confidentiality to establish coverage under the stipulated protective order.").

V. There Is No Basis for Natera's June 27, 2018 Email To Remain Under Seal.

The compelling reason standard — rather than the lower, yet still stringent, good cause standard — applies to whether Natera's email should remain under seal. That email was tendered as a Court exhibit during trial and is attached to Guardant's pending motion for attorneys' fees a motion that, in the Ninth Circuit's terminology, "is more than tangentially related to the merits of [this] case." Ctr. for Auto Safety, 809 F.3d at 1101.

Natera has no compelling reason for the June 27, 2018 Email to remain under seal. The email is now nearly 7 years old. See, e.g., Marsteller v. MD Helicopter Inc., 2018 WL 4679645, at *2 (D. Ariz. Sept. 28, 2018) ("MDHI fails to explain how disclosure of pricing, compensation, and contract information that is several years old would inflict a financial or competitive injury."); In re NCAA Student-Athlete Name & Likeness Licensing Litig., 2013 WL 3014138, at *2 (N.D. Cal. June 17, 2013) (denying motion to seal because the document is "eight years old, and NCAA fails to articulate what specific harm an outdated document will have on its current or future operations"). The email contains no conceivable trade secrets or any other type of competitively sensitive information. The email contains no confidential patient medical records, or anything that would implicate a right to privacy. In sum, Natera's email does not contain any of the types of sensitive information that are typically sealed by a court. See Skky, LLC v. Facebook, Inc., 191 F. Supp. 3d 977, 981 (D. Minn. 2016) ("On its face, the information Defendants seek to file under seal is not the type of sensitive information that might typically be subject to an order to seal, such as financial data, proprietary or trade secret information, or personal health details.").

Indeed, Natera seems to recognize that there is no basis to keep this email under seal. When the Court accepted Natera's email as a tendered, but not admitted, exhibit, Natera made no argument for the email to be under seal. See Trial Tr. vol. 8, at 1955-56. When Guardant attached the email to its motion for attorney's fees, Dkt. 885, Natera filed no statement or declaration pursuant to Local Rule 79-5 explaining why the email should remain sealed. Local Rule 79-5(f)(3) states that "[a] failure to file a statement or declaration may result in the unsealing of the

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provisionally sealed document without further notice to the Designating Party." Thus, despite multiple opportunities, Natera has taken no action to justify sealing this email. Natera's lack of action should constitute a waiver of any objection by Natera to unsealing the email.

Natera may have designated the email "confidential" out of fear of public embarrassment or further scrutiny of the Reinert Study's integrity. But the fact that public access "may lead to a litigant's embarrassment, incrimination, or exposure to further litigation" is not itself a compelling reason to seal a document. Kamakana, 447 F.3d at 1179. See also Fed. Trade Comm'n v. Kochava Inc., 2023 WL 7283113, at *7 (D. Idaho Nov. 3, 2023) ("Certainly, the FTC's allegations cast Kochava's services in an unfavorable light. But that is no reason to shield the complaint from public view."); Marden's Ark, Inc. v. UnitedHealth Grp., Inc., 534 F. Supp. 3d 1038, 1049 (D. Minn. 2021) ("Though the information may be embarrassing, it reveals nothing about UHG's proprietary system or contracts."). Thus, in unsealing communications between a pharmaceutical company and the FDA, the district court explained: "First, disclosure of additional safety and efficacy information about Paxil serves to promote public health rather than endanger it. Further, the fact that disclosure may allow competitors to paint Paxil in an unfavorable light to healthcare professionals is insufficient to render the information confidential." Forst v. Smithkline Beecham Corp., 639 F. Supp. 2d 948, 957 (E.D. Wis. 2009).

Beyond Natera's inability to present a compelling reason to seal the June 27, 2018 Email, the overriding public interest requires it to be unsealed. "[T]he Ninth Circuit does not require a party seeking public disclosure of sealed documents to provide an independent public interest in those documents." Chi v. Univ. of S. Cal., 2019 WL 3315282, at *7 (C.D. Cal. May 21, 2019). To do so would "impermissibly shift the evidentiary burden" from the party seeking to seal documents. Id. Nevertheless, there is a strong public interest in evidence showing Natera's senior executives knew that what was done in the Reinert Study was wrong and improper.

Natera relied on the Reinert Study for all the advertisements at issue in this case, advertisements that Natera distributed to virtually every oncologist in the U.S. Natera used the Reinert Study to persuade doctors and patients that Signatera was safe and reliable. Natera relied on the Reinert Study to obtain Medicare coverage for Signatera. And Natera continues to rely on the Reinert Study today in its marketing materials for Signatera. *See* Natera, *Signatera*, https://www.natera.com/oncology/signatera-advanced-cancer-detection/ (last visited May 28, 2025) (citing as Reference No. 1 the Reinert Study).

Yet, to Guardant's knowledge, Natera has not issued any public correction of the Reinert Study, or otherwise contacted the editors of JAMA Oncology to revise or rescind the Reinert Study. The public has a strong interest in learning how the Reinert Study was manipulated and that Natera's senior executives knew that it would misrepresent the performance of Signatera but did it anyway. The courts have recognized similar public interests in unsealing documents. For example, in products liability litigation against Eli Lilly, the district court unsealed a large number of records because (1) "[t]he documents are now so outdated that unsealing will not significantly harm Lilly" and (2) "[p]ublic access is now advisable because this litigation involves issues of great public interest, the health of hundreds of thousands of people, fundamental questions about our system of approval and monitoring of pharmaceutical products, and the funding for many health and insurance benefit plans. Public and private agencies and organizations have a right to be informed." In re Zyprexa Prods. Liab. Litig., 253 F.R.D. 69, 208-09 (E.D.N.Y. 2008), rev'd on other grounds sub nom. UFCW Loc. 1776 v. Eli Lilly & Co., 620 F.3d 121 (2d Cir. 2010). The circumstances are similar here. The June 27, 2018 Email exposes an issue of great public interest that implicates the accuracy of the clinical validation study for a diagnostic test used by doctors and cancer survivors across the country, the cost of which is often reimbursed by Medicare or commercial health insurance companies.

VI. <u>CONCLUSION</u>

Guardant respectfully asks the Court to unseal the June 27, 2018 Email.

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⁵ See also In re Application of Consumer Watchdog, 2024 WL 2104448, at *3 (C.D. Cal. Apr. 11,

2024) ("These questions warrant public scrutiny to determine the extent to which wrongdoers have been held accountable and the extent to which the affected agencies have been reformed."); Chi,

2019 WL 3315282, at *8 ("[T]he public's interest in gaining access to all pertinent information

about Dr. Tyndall's actions, and in particular USC's knowledge of those actions and response thereto, overcome any compelling reasons to seal these records pursuant to a right of privacy